



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

2015 Parenteral Drug Association/Food and Drug Administration Joint Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), is announcing a public conference, to be held in co-sponsorship with the Parenteral Drug Association (PDA), entitled "Mission Possible: Patient-Focused Manufacturing, Quality, and Regulatory Solutions." The conference will cover current issues affecting the industry as well as explore strategies to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies, and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

Date and Time: The public conference will be held on September 28, 2015, from 7 a.m. to 7:30 p.m.; September 29, 2015, from 7 a.m. to 9:30 p.m.; and September 30, 2015, from 7 a.m. to 12:30 p.m.

Location: The public conference will be held at the Renaissance Washington Hotel, 999 Ninth Street, NW., Washington, DC 20001, 202-898-9000, FAX: 202-289-0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 150, Bethesda, MD 20814, 301-656-5900, ext. 111, FAX: 301-986-1093, email: info@pda.org; or Ken Nolan, Office of Communications, Food and Drug Administration 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8629, email: kenneth.nolan@fda.hhs.gov.

Accommodations: Attendees are responsible for their own accommodations. To make reservations, contact the Renaissance Washington Hotel (see Location) and reference "the 2015 PDA/FDA Joint Regulatory Conference" to receive the PDA group rate. Room rates are: Single: \$305 plus 14.5 percent State and local taxes. Requests will be processed on a first-come, first-served basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis beginning at 1 p.m. on September 27, 2015, and at 7 a.m. from September 28 through 30, 2015. The cost of registration is as follows:

Cost of Registration			
Affiliation	Before July 19, 2015	July 19-August 18, 2015	After August 18, 2015
Premier Package (Includes Conference and Workshop Registration)			
Member	\$3,240	\$3,490	\$3,740
Nonmember	\$3,599	\$3,849	\$4,099
Conference Only			
Member	\$1,895	\$2,095	\$2,295
Nonmember	\$2,154	\$2,354	\$2,554
Government/Health Authority Member	\$700	\$700	\$700
Government/Health Authority Nonmember*	\$800	\$800	\$800
Academic Member	\$700	\$700	\$700
Academic Nonmember*	\$800	\$800	\$800
Student Member	\$280	\$280	\$280
Student Nonmember*	\$310	\$310	\$310

*For this member type, online registration is not available and must be faxed in.

Please visit PDA's Web site: www.pda.org/pdafda2015 to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

If you need special accommodations due to a disability, please contact Wanda Neal (see Contact), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to "PDA." Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 150, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: www.pda.org/pdafda2015.

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see [Contact](#)).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Product Quality
- Data Integrity
- Breakthrough Therapies
- Regulatory Challenges and Opportunities
- Lifecycle Management
- Clinically Relevant Specifications
- Food and Drug Administration Safety and Innovation Act
- Quality Metrics/Quality Culture

- Manufacturing of the Future With Submissions
- Continuous Verification and Validation
- Continuous Manufacturing
- "Fishbowl" Role Play
- Quality Systems
- Contract Manufacturing Organizations
- Maturity of Quality Systems
- Investigations
- Case Studies for Quality
- Quality Submissions
- Prescription Drug User Fee Act
- Risk-Based Control Strategies
- Supply Chain
- Quality Risk Management Systems
- Drug Shortages
- Customer Complaint Reviews and Trending
- Human Factors
- Office of Pharmaceutical Quality and Program Alignment Group
- Patient Perspective
- Compliance Update
- Center Initiatives--Regulatory Submission Update

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes

working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by government agencies to small businesses.

Dated: March 4, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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